SPL Update — July 2006

Beginning June 30, 2006, content of labeling submitted to the Agency should be in the new format required in the Physician Labeling Final Rule (PLR) (21 CFR 201.56 & 57).[1]

- FDA expects marketing applications and efficacy supplements to be submitted in Structured Product Labeling (SPL) using the format required in the PLR.
- If anyone anticipates not being able to include the Highlights data elements in SPL with their submission, they should contact us at SPL@FDA.hhs.gov, and we will provide them with individual assistance.
- Applicants should be able to address any final technical issues related to submitting SPL with the Highlights data elements during the 6 months following implementation of the final rule in June 2006. During this initial implementation phase (until the end of the year), FDA will work with applicants to correct SPL deficiencies and will not refuse to file a marketing application or efficacy supplement, or delay approval of such an application, because of such deficiencies.

[1] For a copy of the Physician Labeling Final Rule, see the *Federal Register*, Vol. 71, No. 15; Tuesday, January 24, 2006.